UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

UNITED STATES OF AMERICA v. DOUGLAS J. JORGENSEN	No.

COMPLAINT

NOW COMES Plaintiff, the United States of America, on behalf of its agency, the U.S. Drug Enforcement Administration ("DEA"), and hereby files the instant Complaint and in support thereof alleges as follows.

I. SUMMARY OF ACTION

1. The United States brings this civil action against defendant, Douglas J. Jorgensen, D.O., to recover civil penalties under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, (the "CSA"), for defendant's violations of the CSA. A primary purpose of the CSA is to ensure that controlled substances are completely accounted for when dispensed and distributed. Failure to abide by the CSA's dispensing requirements undermines the comprehensive regulatory structure envisioned by Congress and administered by the DEA. From about September 25, 2018 through about April 26, 2019, the defendant violated the CSA by causing electronic prescriptions for Schedule II controlled substances to be dispensed by another person using his DEA Registration and hard token while the defendant was travelling outside of the United States.

2. The United States seeks civil penalties under the CSA, 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5, for each instance where the defendant caused an electronic prescription to be issued for a Schedule II controlled substance by another person using his DEA Registration and hard token while the defendant was travelling

outside of the United States, all in violation of 21 U.S.C. § 842(a)(1) and 829(a) and (e); and 21 C.F.R. §§ 1306.04(a); 1311.120(b)(12) (only a prescribing physician may sign an electronic prescription); 1311.135(a) (same).

II. JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over the United States' CSA claims pursuant to 28 U.S.C. §§ 1331, 1345, and 1355, as well as under the civil provisions of the CSA, 21 U.S.C. § 842(c)(1).

4. This Court has personal jurisdiction over the defendant because, he, at all times relevant to this action, resided in and/or transacted business in this District.

5. Venue is proper in this District under 28 U.S.C. §§ 1391(b)(2) because the defendant, at all times relevant to this action, transacted business in this District and/or because a substantial part of the acts or omissions giving rise to the claims occurred in this District.

III. PARTIES

6. Plaintiff is the United States, acting on behalf of its agency, the DEA.

7. At all times relevant to this action, the defendant:

(a) was a Maine resident, a United States citizen, and a licensed osteopathic physician ("D.O") who maintained a private medical practice in Manchester, Maine;

(b) held a DEA Registration, pursuant to 21 U.S.C. §§ 822 and 823; and

(c) had a place of business in Manchester, Maine, that was a controlled premise within the meaning of 21 U.S.C. § 880(a) and 21 C.F.R. § 1316.02(c).

IV. THE CONTROLLED SUBSTANCES ACT

8. All persons who dispense controlled substances are regulated by the CSA, which establishes a closed system of controls over all stages of the dispensing and distribution of controlled substances in the United States.

9. The Attorney General has promulgated regulations for "the registration and control of the. . . dispensing of controlled substances." 21 U.S.C. § 821. "[C]ontrolled substances are strictly regulated. . . . because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under the proper circumstances." 75 Fed. Reg. 61,613 – 61,617 (Oct. 6, 2010).

10. Under the CSA, the DEA regulates pharmaceutical drugs that are classified as controlled substances because of their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision.

11. Controlled substances are classified in five schedules according to the characteristics of each substance. Schedule II controlled substances have a high potential for abuse and significant restrictions because of their potential for abuse. 21 U.S.C. § 812(b)(2).

12. Under the CSA, all dispensers of controlled substances must register with DEA and maintain strict accounting for such transactions. "Dispense" includes, among other things, the issuance of a prescription by a physician. 21 U.S.C. §§ 802(10) and (21). Thus, physicians who prescribe controlled substances must have a DEA Registration. 21 U.S.C. § 822(a)(2); *see also* 21 C.F.R. § 1300.01(b) ("Dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.").

13. For a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose by a physician acting in the usual course of professional practice. *United States v. Moore,* 423 U.S. 122 (1975); 21 C.F.R. § 1306.04(a). The responsibility for the proper dispensing of controlled substances is upon the prescribing physician and the pharmacist who fills the prescription. 21 C.F.R. § 1306.04(a).

14. The CSA provides that a controlled substance in Schedule II may only be dispensed by a pharmacy pursuant to a written prescription, except in emergencies. 18 U.S.C. § 829(a). In 2009, the CSA, was amended to allow for the dispensing of controlled substances electronically by means of the Internet. Under the amendment, a "valid prescription" is defined as: "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner." 21 U.S.C. § 829(e)(2)(A). The phrase "in person medical evaluation" is defined as "a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals." 21 U.S.C. § 829(e)(2)(B)(i). The phrase "covering practitioner" is defined as a "practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who (i) has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and (ii) is temporarily unavailable to conduct the evaluation of the patient." 21 U.S.C. § 829(e)(2)(C)(i) & (ii).

15. A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 C.F.R. § 1306.03(a)(1).

16. All prescriptions for controlled substances must be dated as of, and signed on, the day when issued and must bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and DEA Registration number of the issuing practitioner. 21 C.F.R. § 1306.05(a)

17. A prescription for Schedule II controlled substance cannot be refilled. 21 C.F.R. § 1306.12(a).

18. A physician issuing an electronic prescription must retain sole possession of his hard token (used for two-factor authentication in issuing electronic prescriptions), and must not share the password or other knowledge factor, or biometric information, with any other person. 21 C.F.R. § 1311.102(a).

19. A physician must not allow any other person to use his hard token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 C.F.R. § 1311.102(a).

20. An electronic prescription application must not permit a practitioner – other than the prescribing practitioner whose DEA number is listed on the prescription as the prescribing practitioner and who has indicated that the prescription is ready to be signed – to sign the prescription. 21 C.F.R § 1311.120(b)(12).

21. In order to create a controlled substance prescription, the electronic prescription application may allow the registrant or his agent to enter data for a

controlled substance prescription, provided that only the registrant may sign the prescription. 21 C.F.R. § 1311.135(a).

22. Pursuant to the CSA, dispensing a controlled substance in violation of the CSA creates liability for a civil penalty for each violation. 21 U.S.C. §§ 842(a)(1) and 842(c)(1)(A).

V. FACTUAL BACKGROUND

A. The DEA's Investigation of Defendant

23. On September 25, 2019, the DEA applied for and was granted an administrative inspection warrant pursuant to 21 U.S.C. § 880 by the United States District Court for the District of Maine.

24. The administrative inspection warrant authorized the DEA to perform a search of the defendant's controlled premises for the purpose of inspecting, copying, and verifying its controlled substances records.

25. DEA Diversion and Special Agents executed the administrative inspection warrant and performed a search of the defendant's controlled premises on September 25, 2019. The administrative inspection warrant was returned on October 7, 2019.

26. DEA obtained certified public records from U.S. Customs and Border Protection for the defendant's international travel between August 11, 2018 and April 27, 2019 based upon his use of his passport at border inspection stations that revealed the following:

Date	Depart Location	Arrive Location	Out/In
9/25/2018	Douglas Charlotte	Montego Bay Jamaica	O
9/29/2018	Montego Bay Jamaica	Philadelphia	I
2/25/2019	Boston	London/Heathrow	O
3/4/2019	London/Heathrow	Boston	I

4/18/2019	Dulles Intl.	Frankfort Intl.	O
4/26/2019	Munich Airport, Germany	Boston	I

27. Further to the DEA's investigation and execution of the administrative inspection warrant, the defendant's records were inspected, copied, and reviewed. The review revealed that the defendant's DEA Registration and hard token was used to issue 316 electronic prescriptions for Schedule II controlled substances on dates when the defendant was outside of the United States on international travel.

COUNT I: DISPENSING VIOLATIONS

(21 U.S.C § 842(a)(1))

28. Paragraphs 1 through 27 are realleged as though fully set forth herein.

29. Defendant failed to comply with the requirements of the CSA by causing electronic prescriptions to be issued for a Schedule II controlled substance by another person using his DEA Registration and hard token while the defendant was travelling outside of the United States, in violation of 21 U.S.C. § 842(a)(1) and 829(a) and (e); and 21 C.F.R. §§ 1306.04(a); 1311.120(b)(12) (only a prescribing physician may sign an electronic prescription); 1311.135 (same).

30. Each of the dispensing violations was in contravention of 21 U.S.C. § 842(a)(1) such that defendant is subject to a civil penalty for each violation. 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

WHEREFORE, Plaintiff the United States requests that judgment be entered in its favor and against defendant on Count One, civil penalties per each violation pursuant to 21 U.S.C. § 842(c)(1)(A), and all other relief this Court deems just and proper.

Dated: August 1, 2023
Bangor, Maine

Respectfully submitted,

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